General

Guideline Title

Antibiotic prophylaxis in spine surgery.

Bibliographic Source(s)

North American Spine Society (NASS). Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2012. 72 p. [168 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Watters WC III, Baisden J, Bono C, Heggeness M, Resnick D, Shaffer WO, Toton J. Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2007. 84 p. [104 references]

The guideline recommendations will be reviewed every three years by an EBM-trained multidisciplinary team and revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the guideline.

Recommendations

Major Recommendations

The grades of recommendations (A-C, I) and levels of evidence (I-V) are defined at the end of the "Major Recommendations" field.

Recommendations Regarding Antibiotic Prophylaxis in Spine Surgery

Efficacy

For patients undergoing open spine surgery, does antibiotic prophylaxis result in decreased infection rates compared to patients who do not receive prophylaxis?

Preoperative prophylactic antibiotics are suggested to decrease infection rates in patients undergoing spine surgery.

Grade of Recommendation: B

For a typical, uncomplicated lumbar laminotomy and discectomy, a single preoperative dose of antibiotics is suggested to decrease the risk of infection and/or discitis.

Grade of Recommendation: B

For patients undergoing open spine surgery, does antibiotic prophylaxis result in decreased infection rates compared to patients who do

not receive prophylaxis?

Prophylactic antibiotics are suggested to decrease the rate of spinal infections following uninstrumented lumbar spinal surgery.

Grade of Recommendation: B

For patients undergoing open spine surgery with spinal implants, does antibiotic prophylaxis result in decreased infection rates as compared to patients who do not receive prophylaxis?

Prophylactic antibiotics may be considered to decrease the rate of infections following instrumented spine fusion.

Grade of Recommendation: C

What rate of surgical site infections can be expected with the use of antibiotic prophylaxis, considering both patients with and patients without medical comorbidities?

CONSENSUS STATEMENT: Despite appropriate prophylaxis, the rate of surgical site infections in spine surgery is 0.7%–10%. The expected rate for patients without comorbidities ranges from 0.7%–4.3% and for patients with comorbidities ranges from 2.0%–10%. Current best practice with antibiotic protocols has failed to eliminate (reach an infection rate of 0.0%) surgical site infections.

Despite appropriate prophylaxis, diabetes carries an increased infection rate compared with non-diabetic patients.

Level of Evidence: III

There is insufficient evidence to make a statement regarding the impact of obesity on the rate of surgical site infection in prophylaxed patients.

Level of Evidence: I (Insufficient)

Protocol

For patients receiving antibiotic prophylaxis prior to open spine surgery, what are the recommended drugs, their dosages, administration routes and timing resulting in decreased postoperative infection rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery. In typical, uncomplicated spinal procedures, the superiority of one agent, dose or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure and issues of antibiotic resistance should be considered.

Grade of Recommendation: B

In typical, uncomplicated spinal procedures, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested.

Grade of Recommendation: B

CONSENSUS STATEMENT: In patients with comorbidities or for those undergoing complicated spine surgery, alternative prophylactic regimens including redosing, gram-negative coverage or the addition of intrawound application of vancomycin or gentamicin, are suggested to decrease the incidence of surgical site infections when compared to standard prophylaxis regimens.

CONSENSUS STATEMENT: Comorbidities and risk factors reviewed in the literature include obesity, diabetes, neurologic deficits, incontinence, preoperative serum glucose level of >125 mg/dL or a postoperative serum glucose level of >200 mg/dL, trauma and prolonged multilevel instrumented surgery. See the original guideline document for information on support studies that further define the risk factors associated with surgical site infection in spine surgery patients.

For patients receiving antibiotic prophylaxis prior to open spine surgery without spinal implants, what are the recommended drugs, their dosages, administration routes and timing resulting in decreased postoperative infections rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery without spinal implants. In these typical, uncomplicated spinal procedures, the superiority of one agent, dose or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure and issues of antibiotic resistance should be considered.

Grade of Recommendation: B

In typical, uncomplicated open spine surgery without spinal implants, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested.

Grade of Recommendation: B

For patients receiving antibiotic prophylaxis prior to open spine surgery with spinal implants, what are the recommended drugs, their dosages, administration routes and timing resulting in decreased postoperative infections rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery with spinal implants. In these complex spinal procedures, the superiority of one agent, dose or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure and issues of antibiotic resistance should be considered.

Grade of Recommendation: B

CONSENSUS STATEMENT: In patients with risk factors for polymicrobial infection, appropriate broad-spectrum antibiotics are suggested to decrease the risk of infection when instrumented fusion is performed.

What is a reasonable algorithmic approach for antibiotic selection for a given patient?

CONSENSUS STATEMENT: Simple uncomplicated spine surgery (without instrumentation or comorbidities) →1 single preoperative dose of antibiotic of choice with intraoperative redosing as needed.

CONSENSUS STATEMENT: Instrumented spine surgery, prolonged procedures, comorbidities (e.g., diabetes, neuromuscular disease, cord injury or general spine trauma) →1 single preoperative dose of antibiotic of choice + consideration of additional gram-negative coverage and/or the application of intrawound vancomycin or gentamicin.

Redosing

For patients receiving antibiotic prophylaxis prior to open spine surgery, what are the intraoperative redosing recommendations for the recommended drugs (including dosages and time of administration) resulting in decreased postoperative infection rates?

CONSENSUS STATEMENT: Intraoperative redosing within 3–4 hours may be considered to maintain therapeutic antibiotic levels throughout the procedure. The superiority of one drug has not been demonstrated in the literature. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure and issues of antibiotic resistance should be considered.

Discontinuation

For patients receiving antibiotic prophylaxis prior to open spine surgery, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to longer periods of administration?

For typical, uncomplicated cases, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested to decrease the risk of surgical site infection.

Grade of Recommendation: B

Prolonged postoperative regimens may be considered in complex situations (i.e., trauma, cord injury, neuromuscular disease, diabetes or other comorbidities). Comorbidities and complex situations reviewed in the literature include obesity, diabetes, neurologic deficits, incontinence, preoperative serum glucose level of >125 mg/dL or a postoperative serum glucose level of >200 mg/dL, trauma, prolonged multilevel instrumented surgery and other comorbidities.

Grade of Recommendation: C

Wound Drains

For patients receiving antibiotic prophylaxis prior to open spine surgery and who receive placement of wound drains at wound closure, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to discontinuation of antibiotics at time of drain removal?

There is insufficient evidence to make a recommendation for or against the early discontinuation of antibiotic prophylaxis in patients with wound

drains.

Grade of Recommendation: I (Insufficient Evidence)

The use of drains is not recommended as a means to reduce infection rates following single level surgical procedures.

Grade of Recommendation: I (Insufficient Evidence)

Body Habitus

For patients receiving antibiotic prophylaxis prior to spine surgery, should the recommended protocol differ based upon body habitus (e.g., body mass index)?

Obese patients are at higher risk for postoperative infection, when given a standardized dose of antibiotic prophylaxis. In spite of this conclusion, there is insufficient evidence to make a recommendation for or against recommending a different protocol for patients based upon body habitus.

Grade of Recommendation: I (Insufficient Evidence)

Comorbidities

For patients receiving antibiotic prophylaxis prior to open spine surgery, do comorbidities (other than obesity) such as diabetes, smoking, nutritional depletion, immunodeficiencies and concurrent use of antithrombotic therapies alter the recommendations for antibiotic prophylaxis?

CONSENSUS STATEMENT: In patients with comorbidities or for those undergoing complicated spine surgery, alternative prophylactic regimens are suggested to decrease the incidence of surgical site infections when compared to standard prophylaxis regimens.

There is insufficient evidence to make a recommendation for or against the specific alternative regimens that are efficacious. However, promising alternative regimens that have been studied include redosing, gram-negative coverage and the addition of intrawound application of vancomycin or gentamicin.

Grade of Recommendation: I (Insufficient Evidence)

For patients with a history of methicillin-resistant Staphylococcus aureus *(MRSA) infection, does prophylaxis with vancomycin reduce infections with MRSA compared to other antimicrobial agents?*

There is insufficient evidence to make a recommendation for or against the prophylactic use of vancomycin compared with other antimicrobial agents to reduce infections with MRSA.

Grade of Recommendation: I (Insufficient Evidence)

Complications

Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment?

CONSENSUS STATEMENT: Reported isolated complications related to prophylactic antibiotics include flushing, hypotension, rashes, intramembranous colitis and, most seriously, Stevens-Johnson Syndrome.

What strategies can be implemented to minimize complications/adverse events resulting from the use of prophylactic antibiotics in spine surgery?

CONSENSUS STATEMENT: In typical, uncomplicated spinal procedures, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested to reduce the risk of complications/adverse events.

Reported isolated complications/adverse events related to prophylactic antibiotics are discussed in the "Complications" section in the original guideline document and include: flushing, hypotension, rashes, intramembranous colitis and, most seriously, Stevens-Johnson Syndrome.

Definitions:

Levels of Evidence for Primary Research Questions[1]

Types of Studies				
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (e.g., <80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (e.g., patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of nonconsecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case series[8]	Case series	• Case-control study • Poor reference standard	Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

RCT = randomized controlled trial.

A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.

A combination of results from two or more prior studies.

Studies provided consistent results.

Study was started before the first patient enrolled.

Patients treated one way (e.g., cemented hip arthroplasty) compared with a group of patients treated in another way (e.g., uncemented hip arthroplasty) at the same institution.

The study was started after the first patient enrolled.

Patients identified for the study based on their outcome, called "cases" (e.g., failed total arthroplasty) are compared to those who did not have outcome, called "controls" (e.g., successful total hip arthroplasty).

Patients treated one way with no comparison group of patients treated in another way.

Grades of Recommendation

A: Good evidence (Level I studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Surgical site infections associated with open spine surgery

Guideline Category

Management

Prevention

Clinical Specialty

Infectious Diseases

Neurological Surgery

Orthopedic Surgery

Surgery

Intended Users

Advanced Practice Nurses

Hospitals

Nurses

Physicians

Guideline Objective(s)

- To provide evidence-based recommendations to address key clinical questions surrounding the use of prophylactic antibiotics in spine surgery
- To assist in delivering optimum, efficacious treatment with the goal of preventing surgical infection
- To assist spine surgeons in preventing surgical site infections
- To assist practitioners in their clinical decision-making processes

Target Population

Adults (18 years or older) undergoing spine surgery

Interventions and Practices Considered

Antibiotic prophylaxis for spine surgery

Major Outcomes Considered

Incidence of postoperative infection in patients undergoing spine surgery

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, the North American Spine Society (NASS) has instituted a Literature Search Protocol (see Appendix D in the original guideline document) which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the technical report that accompanies the original guideline document (see the "Availability of Companion Documents" field).

Completion of the Literature Search

Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. NASS maintains a search history in Endnote, for future use or reference.

Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members have identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and/or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

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Patients treated one way with no comparison group of patients treated in another way.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence Analysis

Members have independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members have reviewed each article selected and independently assigned levels of evidence to the literature using the North American Spine Society (NASS) levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. The consensus level (the level upon which two-thirds of reviewers were in agreement) was then assigned to the article.

As a final step in the evidence analysis process, members have identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

Methods Used to Formulate the Recommendations

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because the North American Spine Society (NASS) is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held face-to-face meetings to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate").

Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation

A: Good evidence (Level I studies with consistent findings) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Evidence-Based Guideline Development Committee and the Research Council Director for review and comment. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Submission for Board Approval

Once any evidence-based revisions were incorporated, the drafts were prepared for the North American Spine Society (NASS) Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of antibiotic prophylaxis in spine surgery for prevention of surgical site infections

Potential Harms

Reported isolated complications/adverse events related to prophylactic antibiotics include flushing, hypotension, rashes, intramembranous colitis and, most seriously, Stevens-Johnson Syndrome.

Qualifying Statements

Qualifying Statements

- This guideline does not represent a "standard of care," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.
- This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

Bibliographic Source(s)

North American Spine Society (NASS). Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2012. 72 p. [168 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2007 Jan (revised 2012)

Guideline Developer(s)

North American Spine Society - Medical Specialty Society

Source(s) of Funding

North American Spine Society (NASS)

Guideline Committee

North American Spine Society (NASS) Evidence-Based Clinical Guidelines Committee

Composition of Group That Authored the Guideline

Committee Members: William O. Shaffer, MD (*Chair*); Jamie Baisden, MD; Robert Fernand, MD; Paul Matz, MD

Financial Disclosures/Conflicts of Interest

Disclosure of Potential Conflicts of Interest

All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues and their potential conflicts have been documented in the original guideline document. Participants have been asked to update their disclosures regularly throughout the guideline development process.

Financial Statement

This clinical guideline was developed and funded in its entirety by the North American Spine Society (NASS). All participating authors have disclosed potential conflicts of interest consistent with NASS' disclosure policy. Disclosures are listed below:

- William O. Shaffer, MD Nothing to disclose.
- Paul G. Matz, MD Nothing to disclose.
- Jamie Baisden, MD Nothing to disclose.
- Robert Fernand, MD Nothing to disclose.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Watters WC III, Baisden J, Bono C, Heggeness M, Resnick D, Shaffer WO, Toton J. Antibiotic prophylaxis in spine surgery. Burr Ridge (IL): North American Spine Society (NASS); 2007. 84 p. [104 references]

The guideline recommendations will be reviewed every three years by an EBM-trained multidisciplinary team and revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the North American Spine Society Web site .

Print copies: Available from the North American Spine Society (NASS), 7075 Veterans Boulevard, Burr Ridge, IL 60527; Toll-free: (866) 960-6277. An order form is available from the North American Spine Society Web site .

Availability of Companion Documents

The following is available:

- Antibiotic prophylaxis in spine surgery: technical report. Burr Ridge, IL: North American Spine Society, 2012. 179p. Electronic copies: Available in Portable Document Format (PDF) from the North American Spine Society (NASS) Web site .

Print copies: Available from the North American Spine Society (NASS), 7075 Veterans Boulevard, Burr Ridge, IL 60527; Toll-free: (866) 960-6277. An order form is available from the North American Spine Society Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on April 21, 2008. The information was verified by the guideline developer on June 6, 2008. This summary was updated by ECRI Institute on April 25, 2013.

Copyright Statement

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